SMALL BUSINESS INNOVATION RESEARCH PROGRAM

RELEASE DATE: August 28, 2003

NOTICE: NOT-OD-03-060

National Institutes of Health (NIH) Centers for Disease Control and Prevention (CDC)

Contract Proposal Receipt Date: November 14, 2003

Innovative technologies and methodologies fuel progress in biomedical and behavioral research and represent an increasingly important area of the economy. The Small Business Innovation Research (SBIR) program provides support for research and development (R&D) of new or improved technologies and methodologies that have the potential to succeed as commercial products.

The purpose of this notice is to (1) announce the issuance of the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH CONTRACT PROPOSALS (PHS 2004-1) with a due date of NOVEMBER 14, 2003 for receipt of SBIR CONTRACT proposals; and (2) inform the public about the opportunities that the SBIR program offers to small business concerns as well as to scientists at research institutions. The SBIR legislation requires the Public Health Service (PHS), Department of Health and Human Services, and certain other federal agencies to reserve 2.5 percent of their extramural research or R&D budgets for an SBIR program. The PHS SBIR set-aside requirement for FY 2004 is \$535 million.

The offeror organization must be a small business concern as defined by the Small Business Administration and described in the Solicitation, and the PRIMARY EMPLOYMENT of the principal investigator MUST be with the small business concern at the time of award and during the conduct of the proposed project. In accord with the intent of the SBIR program to increase private sector commercialization of innovations derived from federal R&D, scientists at research institutions can play an important role in an SBIR project by serving as consultants and/or subcontractors to the small business concern.

Generally, one-third of the Phase I budget may be spent on consultant and/or subcontractual costs, and, generally, one-half of the Phase II budget may be spent on such costs. In this manner, a small business concern with limited expertise and/or research facilities may benefit from teaming with a scientist(s) at a research institution; for the scientist(s) at a research institution, this team effort provides support for R&D not otherwise obtained.

The SBIR program consists of the following three phases:

PHASE I: The objective of this phase is to determine the scientific and technical merit and feasibility and potential for commercialization of the proposed research or R&D efforts and the quality of performance of the small business concern, before consideration of further federal support in Phase II. Generally, Phase I SBIR awards do not exceed \$100,000 for direct costs, Facilities and Administrative (F&A) costs, and negotiated fixed fee for a period generally not to exceed six months.

PHASE II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Only Phase I contractors are eligible to apply for Phase II funding, and Phase II proposals may be submitted upon the request of the Contracting Officer ONLY. (However, see "Fast-Track" Initiative below.) Generally, Phase II awards do not exceed \$750,000 for direct costs, F&A costs, and negotiated fixed fee for a period generally not to exceed two years. That is, generally, a two-year Phase II project does not cost more than \$750,000 for that project. Only one Phase II award may be made for any SBIR project.

PHASE III: The objective of this phase is for the small business concern to pursue, with non-SBIR funds, the commercialization of the results of the research or R&D funded in Phases I and II.

"FAST-TRACK" INITIATIVE: (Applicable only to proposals submitted to the National Institutes of Health [NIH] and only if an awarding component indicates it is accepting Fast Track proposals for a particular topic.)

The Fast-Track initiative is an opportunity for small business concerns to submit both a Phase I and Phase II proposal for concurrent peer review. This initiative also has the potential to minimize any funding gap between Phase I and Phase II. Proposals must be prepared in accordance with Phase I and Phase II proposal preparation instructions.

Following are the research topics contained in the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH CONTRACT PROPOSALS (PHS 2001-1) for the contract proposal RECEIPT DATE of NOVEMBER 14, 2003:

NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA) 017 Development of Methodology for Measuring Compliance for Medications

018 Medications Development

024 Development of Correlational Alcohol-Relevant Database from Mouse Transcriptosome and Proteome

- 025 Identification of Genomic, Proteomic, Or Metabolomic Differences Associated with Alcohol-induced Organ Damage and Other Alcohol- related Diseases
- 026 Science Education Materials Development for Kindergarten through 12th Grade
- 027 Biochemical Markers
- 028 Development of Equipment and Materials Related to Activities on the Genetics of Alcohol Metabolism

National Cancer Institute (NCI)

- 181 Clinical Trial Data Collection Using Hand-Held Technology
- 184 Biomedical Informatics System for Basic and Clinical Cancer Research
- 186 Target Based High Throughput Screening for the Identification of Radioprotectors
- 190 New Approaches for the Determination of 3-Dimensional Protein Structure
- 191 Technologies for the Study of Genetic Alterations
- 192 New Technologies for Monitoring the Tumor Micro-environment
- 193 Development of Inhibitory Reagents for the Study of Protein Function
- 194 Development and Application of High-Throughput Proteomics Technologies
- 195 Virtual Microscopy for the Early Detection of Cancer
- 196 Antibody Array for Cancer Detection
- 197 Early Detection Research Network Bioinformatics Research Program (EDRN-BRP)
- 198 Chemical Optimization and Structure-Activity Relationships
- 199 Development of an Analytical Information Management System
- 200 A Software Program to Develop Logic Models
- 201 Research-based Health Information Communications Network Targeting Minority Populations
- 202 Develop ACR BIRADS/BCSC: A Standardized Computerized Mammography Data System

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- 060 Develop New Technologies for Screening and Assessing Drug Abuse and Matching Patients with Appropriate Treatment Services
- 061 Develop Screening and/or Assessment Tools for Multi-Problem Youth
- 062 New Technologies for Epidemiology Research
- 063 Efficient in vivo Delivery System for siRNA
- 064 Nanoscience-based Design of Therapies for Substance Abuse Treatment
- 065 Discovery of New Chemical Probes
- 066 Reagents to Identify Transcription Factors That Define Neural Cell Types
- 067 Development of Novel Approaches in Human Neuroscience
- 068 Virtual Reality for the Neurobiological Study of Drug-Brain-Behavior Interactions and Drug Abuse Treatment
- 069 Design, Evaluation, and Integration of Image Analysis Methods to Facilitate Clinical Neuroimaging in Substance Abuse

National Institute of Environmental Health Sciences (NIEHS)

- 094 Development and Validation of High Throughput In Vitro Estrogen Receptor (ER) and Androgen Receptor (AR) Binding Assays Based on the Use of Recombinant Receptors
- 095 Development and Validation of Metabolically Competent In Vitro Toxicity Test Systems
- 096 Development of an Indoor Allergen Assay for Asthma Studies
- 097 Development of a Comprehensive System to Control Indoor Humidity and Reduce Indoor Allergen Levels in Residential Dwellings
- 098 Mouse Tissue Informatics
- 099 Analysis and Quantification of Eicosinoid and Regulatory Pathways
- 100 Metabonomics of the Liver

National Institute of Mental Health (NIMH)

043 Development of Post-Postpartum Depression Training and Support

Materials for Primary Care Providers

- 044 Interactive Web-Based Networking Tool For Linking Services And Interventions Research Training And Education Programs
- 045 Suicide Prevention Materials and Training for Criminal and Civil Court Systems
- 046 Development of Educational Models and Procedures to Improve the Quality of Mental Health Services and Interventions Research Mentoring
- 047 New methods for Rating Patients, Training Raters, and Assessing Reliability for Autism Spectrum Disorders
- 048 Source Documents On Handheld Devices For Clinical Trials In Autism: Adaptive Functioning, Global Functioning, Quality Of Life, Behavior Ratings, and/or Symptom Ratings
- 049 Adapting Existing Curricula for Promoting Social and Adaptive Functioning in Individuals with Autism Spectrum Disorders
- 050 Autism Caregivers: Developing Training and Educational Materials That Adapt Empirically-Based Caregiver Support Strategies
- 051 Multi-Media Training and Education Materials for Cost-Effectiveness Analysis in Mental Health Services Research
- 052 Interactive Tools for State Mental Health Agencies around the Implementation of Evidence-Based Practices
- 053 Development of Tools and Monitoring Systems for the Implementation of Scientifically-Based Interventions to Reduce Mental Health Problems
- 054 Neurocognitive Assessment in Schizophrenia

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (NCCDPHP)

- 013 High Through-Put Method to Isolate Tobacco and Tobacco-Derived Cigarette Components
- 014 Method to Screen Tobacco Products for Reduced-Harm or Reduced-Exposure Claims
- 017 Culturally Tailored, Community-Based, Behavioral Change Intervention for at Risk Minorities

- 018 Influencing Healthy Food Choices with a Skill Building Interactive Web Tool/CD-Rom
- 019 Multi-Modal Based Intervention to Promote Healthier Lifestyles in at Risk Youth
- 020 An Interactive Web-Tool Cookbook Approach Toward Increasing Consumption of Fruit and Vegetables
- 021 Consumer Tools for Selecting Diabetes Health Care Coverage

National Center for HIV, STD AND TB Prevention (NCHSTP)

- 016 Technology to Facilitate the Rapid Identification of Antibiotic Resistance among Neisseria Gonorrhoeae in the Absence of Culture
- 017 HPV and Pap Smear Screening Educational Materials for Low Literacy Population
- 018 Development of Novel HIV-1 Envelope Immunogens for Vaccine Development
- 019 Development of Novel Genotyping Procedures for Mycobacterium Tuberculosis
- 020 New Laboratory Tests for Tuberculosis and Detection of Drug Resistance

National Center for Environmental Health (NCEH)

- 004 Environmental Health/Anti-Chemical Terrorism -- Rapid Field Tests for Human Exposure
- 005 Detection of Human Exposure to Aflatoxins and Other Mycotoxins from Food or as Chemical Warfare or Terrorism Agents
- 006 Rapid Field Tests or Continuous Monitors for Arsenic in Drinking Water
- 007 Rapid Field Tests for Iodine Levels in Urine and Salt
- 008 Coronary Heart Disease
- 009 Enhancement of Blood Glucose Meters to Improve Management of Diabetes
- 010 Rapid Field Tests for Vitamin A Status
- 011 Rapid Field Tests for Iron Deficiency, Iron Deficiency Anemia, and Hemochromatosis
- 012 Improved Tests for Zinc Status and Zinc Body Stores in Humans

013 Improving Assessment of Children's Exposure to Toxic Substances

National Immunization Program (NIP) 016 Develop Methods to Enhance Administration of Vaccines, Including Live Virus Vaccines, Through the Respiratory Tract

018 Melting Device for Safe Sharps Disposal in Developing Countries

INQUIRIES

Eligibility requirements, definitions, submission procedures, review considerations, contract proposal forms and instructions, and other pertinent information, including the "Fast-Track" Initiative, are contained in the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH CONTRACT PROPOSALS (PHS 2004-1) for the proposal receipt date of November 14, 2003. The PHS SBIR Contract Solicitation PHS 2004-1, including proposal forms, is available electronically through the National Institutes of Health's "Small Business Funding Opportunities" home page at http://grants.nih.gov/grants/funding/sbir.htm. See SBIR Phase I Contract Solicitation PHS 2004-1 (PDF http://grants.nih.gov/grants/funding/SBIRContract2004/PHS2004-1.pdf] or MS Word [http://grants.nih.gov/grants/funding/SBIRContract2004/PHS2004-1.doc]). Be sure to use the appropriate CONTRACT PROPOSAL forms as they differ from the PHS 398 GRANT application forms.

Note: The SBIR Phase I Contract Solicitation will only be available via electronic means. Potential offerors are encouraged to check the NIH SBIR/STTR home page for updates on the program. Any updates or corrections to the solicitation will be posted there.

Contracting Officers

Any small business concern that intends to submit an SBIR contract proposal under this Solicitation should provide the appropriate contracting officer(s) with early, written notice of its intent, giving its name, address, telephone, and topic number(s). If a topic is modified or canceled before this Solicitation closes, only those companies that have expressed such intent will be notified.

NATIONAL INSTITUTES OF HEALTH (NIH)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) National Center for HIV, STD, and TB Prevention (NCHSTP) National Center for Environmental Health (NCEH) National Immunization Program (NIP)

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Those interested in the PHS SBIR/STTR GRANT program may access electronically (http://grants.nih.gov/grants/funding/sbir.htm) the OMNIBUS SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) and SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) GRANT APPLICATIONS (PHS 2003-2). There is one GRANT APPLICATION receipt date (December 1, 2003) remaining for calendar year 2003.

To better understand the differences between grants and contracts, see http://grants.nih.gov/grants/funding/contracts vs grants.htm.

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